510(k) Summary

Applicant Contact Information:

OCT - 9 2009

Applicant:	Instrumentation Laboratory Co.
Address:	113 Hartwell Avenue Lexington, MA 02421
Contact Person:	Carol Marble, Regulatory Affairs Director
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Preparation Date:	February 27, 2009

Device Trade Names (Products Sold Separately):

HemosIL® INR Validate

HemosIL® ISI Calibrate

ISIweb Software

Device Regulatory Information:

Controls:	Class II	Product Code: GGN	21 CFR 864.5425
Calibrators:	Class II	Product Code: JIS	21 CFR 862.1150

Predicate Devices:

HemosIL INR Validate	K010750	Pacific Hemostasis INR Control Plasmas
HemosIL ISI Calibrate	K041905	HemosIL Calibration Plasma

Device Intended Uses:

- HemosIL INR Validate is a tri-level quality control intended to monitor the accuracy of INR (International Normalized Ratio) reporting with designated HemosIL PT reagents on IL Coagulation Systems in conjunction with the ISIweb software.
- HemosIL ISI Calibrate is a set of four certified plasmas intended to establish a laboratory's instrument/reagent specific local ISI (International Sensitivity Index) and Mean Normal Prothrombin Time (MNPT) with designated HemosIL PT reagents on IL Coagulation Systems in conjunction with the ISIweb software.
- ISIweb Software is a web-based service to customers, used in conjunction with HemosIL INR Validate and HemosIL ISI Calibrate with designated HemosIL PT reagents on IL Coagulation Systems, whereby the PT seconds and INR results can be entered and calculated through a web-based interface (ISIweb software).

Device Descriptions:

- HemosIL INR Validate

  The HemosIL INR Validate set consists of three control plasmas (Levels 1-3) with assigned INR (International Normalized Ratio) Reference Values in the range of 1.6 – 5.0, prepared using lyophilized citrated plasma from human donors on stable anti-vitamin K therapy (AVK). The reference INR values for each Level are reagent-specific for the IL coagulation systems. The plasma factors (II, VII, IX, X, PC & PS) in these controls are similar to levels normally expected in plasma from patients undergoing long-term oral anticoagulant therapy, together with the proteins induced by vitamin K antagonists (PIKVA inhibitors).

  The control plasmas of HemosIL INR Validate are run on a local instrument/reagent system using the manufacturer's lot-specific label ISI value and the laboratory's locally established lot-specific Mean Normal Prothrombin Time (MNPT).

  - If the mean INRs of all the controls are within ± 15% of their assigned INR Reference Values as determined through the ISIweb, the PT/INR system is verified.
  - If the mean INRs of the controls exceed ± 15% of their assigned INR Reference Values as determined through the ISIweb a new local ISI calibration is recommended using HemosIL ISI Calibrate. Verification of the new local ISI and MNPT is then performed by running the HemosIL INR Validate control plasmas a second time on the same instrument/reagent system with the local ISI and MNPT.

- HemosIL ISI Calibrate

  The HemosIL ISI Calibrate set contains four calibration plasmas (Levels A-D) with assigned INR (International Normalized Ratio) Reference Values in the range of 0.9 – 5.0 for standardizing the PT test on IL Coagulation Systems. These INR Reference Values are reagent specific for the IL Coagulation Systems. Level A is a lyophilized normal human pool produced from the selected citrated plasmas of healthy donors. Levels B-D are lyophilized citrated plasmas produced from a pool of human donors on long-term oral anticoagulant therapy (anti-vitamin K: AVK). The plasma factors (II, VII, IX, X, PC, & PS) are similar to those levels normally expected in plasma from patients undergoing long term oral anticoagulant therapy together with protein induced by vitamin K antagonists (PIVKA inhibitors).

  The calibrate plasmas from HemosIL ISI Calibrate are run on the laboratory's IL instrument/reagent system to establish a local ISI. The PT (sec) data is entered into the ISIweb, which generates a calibration curve from the PT and the INR Reference Values by plotting an orthogonal regression of LogINR (X-axis) vs. LogPT (Y-axis). The ISI and Mean Normal Prothrombin Time (MNPT) are derived from the slope and y-intercept of the curve as:

$$ISI = 1/slope$$
$$MNPT = 10^{y\text{-intercept}}$$

- ISIweb Software

  When used in conjunction with HemosIL INR Validate, ISIweb will automatically calculate the mean INR for each control level and verify that the mean INR for each control level is within ± 15% of the assigned INR Reference Value.

  When used in conjunction with HemosIL ISI Calibrate, ISIweb will automatically calculate the mean PT and %CV value for each level. If the %CV for each level passes % CV specifications, the ISIweb generates a calibration curve from the PT and INR Reference Values by plotting an orthogonal regression of LogINR (X-axis) vs. LogPT (y-axis).

Statement of Technological Characteristics of the Device Compared to Predicate Devices:

- HemosIL INR Validate is substantially equivalent in performance and intended use to Pacific Hemostasis INR Control Plasmas (K010750).
- HemosIL ISI Calibrate is the same type of device as HemosIL Calibration Plasma and in compliance with establishing a local ISI assignment following CLSI H54-A - Procedures for Validation of INR and Local ISI Calibration of PT/INR Systems or ISTH – Guidelines on preparation, certification, and use of certified plasmas for ISI calibration and INR determination.

Summary Performance Data:

A precision study conducted in accordance to CLSI EP05-A2 (20 days; 2 replicates per run; 2 runs per day; N=80 per level) on the three levels of HemosIL INR Validate and four levels of HemosIL ISI Calibrate using IL HemosIL PT reagents on representative IL Coagulation Systems:

HemosIL INR Validate (Levels 1-3)					
Reagent	**Instrument**	**Level**	**Mean (Seconds)**	**Within-Run % CV**	**Total % CV**
HemosIL RecombiPlasTin	ACL TOP	1	28.1	1.2	1.5
	ACL 10000		27.2	1.0	2.1
	ACL TOP	2	43.5	1.0	2.5
	ACL 10000		41.4	1.3	3.1
	ACL TOP	3	68.3	2.8	3.5
	ACL 10000		65.5	1.0	1.5
HemosIL RecombiPlasTin 2G	ACL TOP	1	22.3	2.0	2.5
	ACL 10000		21.2	0.9	1.9
	ACL TOP	2	33.9	0.9	1.8
	ACL 10000		32.0	1.2	3.0
	ACL TOP	3	53.2	4.1	4.4
	ACL 10000		51.4	1.2	2.0
HemosIL PT-Fibrinogen HS PLUS	ACL TOP	1	24.7	1.3	2.5
	ACL 10000		24.5	0.7	1.7
	ACL TOP	2	35.4	1.6	2.7
	ACL 10000		34.6	1.2	2.2
	ACL TOP	3	50.5	3.5	4.2
	ACL 10000		48.0	1.5	3.4
HemosIL PT-Fibrinogen HS*	ACL 10000	1	21.2	0.9	1.9
	ACL 10000	2	32.0	1.2	3.0
	ACL 10000	3	51.4	1.2	2.0
HemosIL PT-Fibrinogen	ACL TOP	1	16.6	0.4	2.1
	ACL 10000		17.5	0.7	2.2
	ACL TOP	2	21.0	0.4	3.4
	ACL 10000		22.4	0.7	3.6
	ACL TOP	3	27.5	0.4	3.9
	ACL 10000		29.8	1.9	4.1

* Application not currently available for HemosIL PT-Fibrinogen HS on the ACL TOP family.

Summary Performance Data (Cont.):

HemosIL ISI Calibrate (Levels A-D)					
Reagent	**Instrument**	**Level**	**Mean (Seconds)**	**Within-Run % CV**	**Total % CV**
HemosIL RecombiPlasTin	ACL TOP	A	12.1	1.2	1.3
	ACL 10000		11.8	0.6	1.1
	ACL TOP	B	29.5	0.8	1.2
	ACL 10000		27.9	1.3	2.0
	ACL TOP	C	43.7	0.7	1.2
	ACL 10000		42.2	0.7	1.1
	ACL TOP	D	68.8	4.4	4.6
	ACL 10000		66.9	0.8	2.0
HemosIL RecombiPlasTin 2G	ACL TOP	A	11.2	1.5	1.6
	ACL 10000		10.7	0.8	1.2
	ACL TOP	B	23.2	1.2	2.2
	ACL 10000		21.4	1.3	2.2
	ACL TOP	C	33.9	1.0	1.7
	ACL 10000		31.6	1.0	2.0
	ACL TOP	D	50.8	4.4	4.9
	ACL 10000		48.5	1.0	2.2
HemosIL PT-Fibrinogen HS PLUS	ACL TOP	A	13.4	1.0	2.1
	ACL 10000		13.5	1.2	2.1
	ACL TOP	B	24.0	1.8	2.5
	ACL 10000		23.7	1.1	4.2
	ACL TOP	C	35.1	1.2	2.2
	ACL 10000		35.2	1.1	1.8
	ACL TOP	D	50.4	3.4	3.9
	ACL 10000		50.1	0.8	2.0
HemosIL PT-Fibrinogen HS*	ACL 10000	A	10.7	0.1	1.2
	ACL 10000	B	21.4	1.3	2.2
	ACL 10000	C	31.6	1.0	2.0
	ACL 10000	D	48.5	1.0	2.2
HemosIL PT-Fibrinogen	ACL TOP	A	11.7	0.9	1.8
	ACL 10000		11.9	0.8	1.4
	ACL TOP	B	16.0	0.4	2.3
	ACL 10000		16.8	0.7	2.3
	ACL TOP	C	20.7	0.3	2.9
	ACL 10000		22.2	0.9	3.0
	ACL TOP	D	26.6	0.4	3.7
	ACL 10000		28.8	0.4	3.5

* Application not currently available for HemosIL PT-Fibrinogen HS on the ACL TOP family.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

OCT - 9 2009

Instrumentation Laboratory Co.
c/o Carol Marble
Regulatory Affairs Director
113 Hartwell Avenue
Lexington, MA 02421

Re: k090563
Trade/Device Name: HemosIL INR Validate, HemosIL ISI Calibrate, and ISI web software
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN, JIS, JQP
Dated: September 1, 2009
Received: September 2, 2009

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090563

Device Name: HemosIL® INR Validate
HemosIL® ISI Calibrate
ISIweb Software

Indications for Use:

- HemosIL INR Validate is a tri-level quality control intended to monitor the accuracy of INR (International Normalized Ratio) reporting with designated HemosIL PT reagents on IL Coagulation Systems in conjunction with the ISIweb software.
- HemosIL ISI Calibrate is a set of four certified plasmas intended to establish a laboratory's instrument/ reagent specific local ISI (International Sensitivity Index) and Mean Normal Prothrombin Time (MNPT) with designated HemosIL PT reagents on IL Coagulation Systems in conjunction with the ISIweb software.
- ISIweb Software is a web-based service to customers, used in conjunction with HemosIL INR Validate and HemosIL ISI Calibrate with designated HemosIL PT reagents on IL Coagulation Systems, whereby the PT seconds and INR results can be entered and calculated through a web-based interface (ISIweb software).

For *in vitro* diagnostic use.

Prescription Use √ (Part 21 CFR 801 Subpart D) **OR** Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K090563